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10/685,505	10/16/2003	Christine Noel	231893US0	5083

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EXAMINER
LANDAU, SHARMILA GOLLAMUDI

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
06/23/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/685,505	NOEL ET AL.	
	Examiner	Art Unit	
	Sharmila Gollamudi Landau	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6 and 8-20* is/are pending in the application.

4a) Of the above claim(s) *21-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6 and 8-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments and Remarks filed 3/21/08 is acknowledged. Claims **1, 6, 8-20** are directed to the elected invention. Claims 21-24 are withdrawn as being directed to non-elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6, 8-18, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/03952 in further view FR 2771632 to Stoltz or US 20010002257 (English equivalent).

WO '952 teaches skin care composition comprising silicone elastomers and a skin care active. See abstract. The composition may be in an oil-in-water emulsion. See page 32, lines 15-20 and examples. The composition comprises silicone elastomers in an amount of 1-20%. The organopolysiloxane is preferably an addition reaction curing organopolysiloxane in the presence of a platinum catalyst. The instant organopolysiloxane is taught. See pages 10-14. The carrier for the elastomer serves to suspend and swell the elastomer particles to provide elastic, gel-like matrix. The carrier is utilized in an amount of 5-50% and may be volatile or non-volatile oil. See page 14. The composition further comprises thickening agents including carboxylic acid polymers, polyacrylate polymers, polysaccharides, gums, and instant polyacrylamide polymer (Speigel) in the amount of 0.1-5%. See page 19-22 and particularly page 20, line 30 to page 21,

line 7. WO '952 teaches the use of active agents including anti-wrinkles agents such as N-acetyl-derivatives, for instance N-acetyl-cysteine (see page 46, line 24) and antioxidants such as methionine, proline, or lysine in an amount of 0.1-10% to provide UV protection (see page 48, line 20). The composition may be formulated into facial skin cosmetics, eye cosmetics, anti-wrinkle creams, lip cosmetics, foundations, etc. The composition is useful in reducing the appearance of wrinkles, scars, skin roughness, blemishes, pores, etc.

The reference does not teach the instant lipoamino acid.

Stoltz teaches the use of N-acyl amino acids for formulating cosmetic compositions that provides soothing/protecting properties, retards skin aging, and provides disinfecting properties to treat acne. The amino acids taught are undecylenoyl glycine and octanoyl glycine. See abstract.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teaching of WO '952 and Stoltz and utilize the instantly claimed amino acid. One would have been motivated to do so since Stoltz teaches the undecylenoyl glycine and octanoyl glycine provides soothing/protecting properties, retards skin aging, provides disinfecting properties to treat acne and WO'952 teaches anti-wrinkles agents such as amino acid derivatives, the use of antioxidants such as methionine, acne actives, and soothing/skin healing actives. Thus, a skilled artisan would have been motivated to utilize the instant amino acid to provide a cosmetic composition that provides all three skin benefits of treating acne, retarding aging, and soothing the skin in a single formulation. A skilled artisan would have expected success since Stoltz teaches the use of various skin active agents including lipoamino acids.

Response to Rule 132 Declaration

Applicant argues that Robinson teaches a tacky solvent and active agent that is soluble in the tacky solvent. Applicant argues that the instant glycine compounds would not be soluble in the polyol.

Applicant's arguments filed 3/21/08 been fully considered but they are not persuasive. The examiner notes that Robinson teaches the use of tacky solvents such as polyols. However, Robinson is not limited to only hydrophilic solvents or an aqueous system as argued by applicant. The composition is an o/w emulsion, which comprises an oil and water phase. Therefore, lipophilic actives would solubilize in the oil phase. The examiner points out that Robinson teaches the use of water-insoluble actives such as retinol. See page 47. Therefore, clearly Robinson does not preclude the incorporation of lipophilic active agents.

With regard to the motivation to combine the references, the examiner points out that the motivation to combine the references does not need to be the same as applicant's since the combination provides the same product claimed. As set forth in the rejection, Robinson clearly suggests the incorporation of anti-wrinkle agents including amino acids derivatives and Stoltz teaches the undecylenoyl glycine and octanoyl glycine provide several benefits including soothing/protecting properties, retarding skin aging, and providing disinfecting properties to treat acne. Therefore, the motivation to utilize the instant amino acids is for the advantages taught by Stolz. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In instant case, the fact that applicant found the lipophilic acids also stabilize the

composition, art cannot be the basis for patentability when the differences would otherwise be obvious.

Applicant argues that the instant specification and the Rule 132 Declaration of 7/24/07 demonstrate that the claimed glycine derivatives can stabilize an oil-in-water emulsion containing at least 1% of an elastomeric organopolysiloxane.

Regarding the Rule 132 Declaration, it is noted that applicant utilizes triethanolamine to solubilize undecylenoylglycine. The examiner notes that the claims do not require a solvent for the lipophilic amino acid. Clearly this solubilization is a critical element to allow the lipophilic amino acid to function to stabilize the emulsion for the stability of the emulsion. Thus, the claims do not claim a critical element that is required to achieve the unexpected results, i.e. the claims are not commensurate in scope. Applicant has not addressed this. Further, it is noted that the examples in the specification and the Declaration only utilize undecylenoylglycine. However, the instant claims are directed to undecylenoylglycine or capryloylglycine and applicant has not provided the unexpectedness of capryloylglycine compared to the prior art. Applicant has not addressed this. Therefore, it is the examiner's position that the Rule 132 Declaration is not persuasive.

Claims 1, 6, 8-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1055406 or US 6,465,402, the English equivalent in view of Fotinos (6,346,255).

Lorant teaches an oil-in-water emulsion comprising an organopolysiloxane elastomer in the oily phase and a water-soluble polymer in the aqueous phase. The oil-in-water emulsions are stable and thus do not contain a conventionally used surfactant. Lorant teaches emulsifiers are potentially irritating the skin, eyes and scalp and thus it is advantageous to formulate an emulsion

without using emulsifiers to stabilize the emulsion. The compositions provide fresh and comfortable during application to the skin, unlike conventional compositions. See abstract and column 1, lines 18-36. Lorant teaches the use of α, ω dimethylvinylpolydimethylsiloxane. See column 4, line 50 and the elastomer gel is utilized in an amount of 0.03-40% and preferably 1.5-20%. See column 5, lines 59-66. The water-soluble polymers that are suitable include carboxyvinyl polymers; acrylic or methacrylic copolymers; natural gums; polysaccharides; acrylamide polymers and copolymers; vinyl ether copolymers; or cationic polymers, such as polyquaternium. Preferable acrylamide copolymers include the crosslinked copolymer of acrylamide and of 2-acrylamido-2-methylpropanesulphonic acid, in particular the mixture sold under the name Sepigel 305. The polymer is utilized in an amount from 0.1 to 10%, preferably 0.2 to 5%, and more preferably from 0.5 to 2%. See column 6, line 5 to column 9, line 40. The oils utilized in the oil phase include non-volatile and volatile oils and the oily phase can range from 1 to 50%. See column 9, line 40 to column 10, line 25. The composition comprises active agent in the amount of 0.01-30% and may be antioxidants, lipophilic active agents, etc. Preferably the active agents include moisturizing agents; keratolytic agents; salicylic acid and its derivatives; vitamins; depigmenting agents; slimming agents; screening agents; and any active principle appropriate for the final purpose of the composition. See column 10, lines 32-60. The composition suitable for treating dry skin and/or dry lips. See column 11, lines 1-7.

Lorant does not teach the use of the instant lipophilic amino acids.

Fotinos teaches improving skin appearance with a skin permeation enhancer and an active agent. See abstract. Fotinos teaches the use of various lipoamino acids such as acylation products, which are anti-elastase and anti-collagenase agents (anti-wrinkle agents); the use of

lipoamino acids such as lysine and lauroylmethionine as antioxidants; lipoamino acids such as instant capryloyl glycine as seboregulators; lipoamino acids such as lysine PCA and related compound as hydratives. See column 7, lines 36-65.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teaching of Lorant and Fotinos and utilize lipoamino acids as the active agent in Lorant's composition. One would have been motivated to do so since Fotinos teaches lipoamino acids have a large number of applications in the cosmetic field including anti-wrinkle agents, antioxidants, hydrating agents, and seboregulators and Lorant teaches the use of any skin active agent including antioxidants and moisturizing agents, depending on the final purpose of the composition. Therefore, the selection of the active agent is prima facie obvious depending on the desired aesthetic benefit provided by the skin care composition. Furthermore, a skilled artisan would have been motivated to utilize capryloyl glycine in particular if one desired to provide a composition that controls sebum, which causes acne.

Response to Arguments and Rule 132 Declaration

Applicant argues that Lorant does not teach or suggest the claimed lipophilic amino acids. Applicant argues that Fontinos does not compensate for Lorant's deficiencies since Fontinos is directed to a patch. Applicant argues that there is not motivation to combine the references with the primary references with the expectation that a stable emulsion would result.

Applicant's arguments filed 3/21/07 have been fully considered but they are not persuasive. Firstly, it is noted that Lorant does not teach a lipophilic amino acid; thus, the examiner relies on Fontinos to cure this deficiency. Lorant suggests the use of antioxidants, moisturizers, and other lipophilic actives as the cosmetic benefit agent. Fontinos teaches

lipoamino acids such as lysine and lauroylmethionine as antioxidants; lipoamino acids such as instant capryloyl glycine as seboregulators; lipoamino acids such as lysine PCA as hydratives. Therefore, for instance, a skilled artisan would have been motivated to utilize lauroylmethionine as the antioxidant of choice if one desired to provide an anti-aging. Similarly, a skilled artisan would have been motivated to utilize capryloyl glycine if one desired to provide a composition that controls sebum. The examiner points out that the motivation to combine the references need not be the same as applicant's, i.e. to increase the stability of the emulsion, since the combination provides the same product. Lastly, the fact that Fontinos teaches the lipophilic amino acids in a pad or patch does not preclude its use in other compositions. The examiner points out that the lipophilic amino acids would have the same function, i.e. as a seboregulator, irrespective of the type of composition and the method of administration, i.e. administering using a patch.

Regarding the Rule 132 Declaration, it is noted that applicant utilizes triethanolamine to solubilize undecylenoylglycine. The examiner notes that the claims do not require a solvent for the lipophilic amino acid. Clearly this solubilization is a critical element to allow the lipophilic amino acid to function to stabilize the emulsion for the stability of the emulsion. Thus, the claims do not claim a critical element that is required to achieve the unexpected results, i.e. the claims are not commensurate in scope. Applicant has not addressed this. Further, it is noted that the examples in the specification and the Declaration only utilize undecylenoylglycine. However, the instant claims are directed to undecylenoylglycine or capryloylglycine and applicant has not provided the unexpectedness of capryloylglycine compared to the prior art. Applicant has not addressed this. Therefore, it is the examiner's position that the Rule 132 Declaration is not persuasive.

Claims 1, 6, 8-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mallo et al (6,197,287) in view of WO 93/05762 or EP 1055406 (US 6,465,402, the English equivalent) respectively.

Mallo et al teach composition in the form of o/w emulsions. See abstract and examples. Example 39 discloses a composition comprising 1.5% dimethicone, 0.3% xanthan gum (hydrophilic polymer), 4% sepicontrol (contains 25% capryloyl glycine), and water among other components. Also note example 29. Oil phase is in utilized in an amount of 15-40%. The oil phase may comprise a mixture of oils including synthetic oils. See column 3, lines 25-30. Mallo teaches organopolysiloxane may be used in the composition as taught in WO 93/05762 or WO 93/21316. See column 5, lines 1-5.

Mallo does not specifically exemplify the organopolysiloxane.

WO 93/05762 teaches o/w emulsions comprising an organopolysiloxane in the instant amount. See examples. WO '762 also teaches the use of the instant hydrophilic polymer.

Lorant teaches an oil-in-water emulsion comprising an organopolysiloxane elastomer in the oily phase and a water-soluble polymer in the aqueous phase. The oil-in-water emulsions are stable and thus do not contain a conventionally used surfactant. Lorant teaches emulsifiers are potentially irritating the skin, eyes and scalp and thus it is advantageous to formulate an emulsion without using emulsifiers to stabilize the emulsion. The compositions provide fresh and comfortable during application to the skin, unlike conventional compositions. See abstract and column 1, lines 18-36. Lorant teaches the use of α, ω dimethylvinylpolydimethylsiloxane. See column 4, line 50 and the elastomer gel is utilized in an amount of 0.03-40% and preferably 1.5-20%. See column 5, lines 59-66. The water-soluble polymers that are suitable include

carboxyvinyl polymers; acrylic or methacrylic copolymers; natural gums; polysaccharides; acrylamide polymers and copolymers; vinyl ether copolymers; or cationic polymers, such as polyquaternium. Preferable acrylamide copolymers include the crosslinked copolymer of acrylamide and of 2-acrylamido-2-methylpropanesulphonic acid, in particular the mixture sold under the name Sepigel 305. The polymer is utilized in an amount from 0.1 to 10%, preferably 0.2 to 5%, and more preferably from 0.5 to 2%. See column 6, line 5 to column 9, line 40. The oils utilized in the oil phase include non-volatile and volatile oils and the oily phase can range from 1 to 50%. See column 9, line 40 to column 10, line 25. The composition comprises active agent in the amount of 0.01-30% and may be antioxidants, lipophilic active agents, etc. Preferably the active agents include moisturizing agents; keratolytic agents; salicylic acid and its derivatives; vitamins; depigmenting agents; slimming agents; screening agents; and any active principle appropriate for the final purpose of the composition. See column 10, lines 32-60. The composition suitable for treating dry skin and/or dry lips. See column 11, lines 1-7.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Mallo and WO '762 and further utilize an organopolysiloxane as suggested by Mallo. Further, it would have been obvious to a skilled artisan to substitute the hydrophilic polymer utilized by Mallo and utilize the instant hydrophilic polymer with a reasonable expectation since both act as gelling agent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Mallo and Lorant and further utilize an organopolysiloxane as suggested by Mallo. One would have been motivated to do so with a reasonable expectation of success since Mallo suggests the incorporation of organopolysiloxane

and Lorant teaches organopolysiloxane allow the stabilization of an emulsion without the use of surfactants which irritate the skin and the organopolysiloxane provide a comfortable feel to the skin, prevent stickiness, and spread well, when applied. Therefore, a skilled artisan would have been further motivated to add an organopolysiloxane for the advantages taught by Lorant. Further, it would have been obvious to a skilled artisan to substitute the hydrophilic polymer utilized by Mallo and utilize the instant hydrophilic polymer with a reasonable expectation since both act as gelling agent.

Response to Arguments

Applicant argues that Mallo relates to an inverted latex product and not the claimed oil-in-water emulsion and there is no motivation would have existed to convert Mallo's desired latex product into the claimed emulsion.

Applicant's arguments filed 3/21/08 have been fully considered but they are not persuasive. Applicant's attention is directed to Example 39 which discloses a composition comprising 1.5% dimethicone, 0.3% xanthan gum (hydrophilic polymer), 4% sepicontrol (contains 25% capryloyl glycine), and water among other components. This composition is an oil-in-water emulsion. The fact that the composition is in a gel form does not preclude it form being an o/w emulsion. Note Mallo discloses, "A topical composition according to the invention, intended to be applied to the skin or mucous membranes of humans or animals can consist of a topical emulsion comprising at least one aqueous phase and at least one oil phase. **This topical emulsion can be of the oil-in-water type. More particularly, this topical emulsion can consist of a fluid emulsion, such as a fluid gel or milk.** The oil phase of the topical emulsion

can consist of a mixture of one or more oils." See column 4, lines 19-26. Further, the instant claim language does not exclude latex.

Regarding the Rule 132 Declaration and purported unexpectedness, the Declaration under 37 CFR 1.132 filed 7/24/07 is insufficient. The Declaration is based on adding capryloylglycine or undecylenoylglycine to a composition comprising an organopolysiloxane polymer; however Mallo teaches a stable cream gel that contains capryloylglycine. Further, Mallo suggests the use of organopolysiloxanes and incorporates the disclosure of WO 93/05762. WO '762 (US 5,470,551 is the US equivalent) teaches the instant polyorganosiloxanes and the instant hydrophylic polymers in o/w emulsions are stable. Further, Lorant also teaches the instant organopolysiloxanes provide stability to oil-in-water emulsions. Therefore, applicant's unexpected results are in fact expected.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila Gollamudi Landau whose telephone number is (571) 272-0614. The examiner can normally be reached on Monday- Friday (8:30-6).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharmila Gollamudi Landau/
Primary Examiner, Art Unit 1611